REMARKS

The application has been amended. Claims 13 and 17 have been amended. Entry of this amendment and reconsideration of the application is respectfully requested.

Undersigned counsel wishes to thank Examiner Prebilic for the courtesies which were extended at a recent personal interview conducted at the U.S. Patent and Trademark Office. At that interview, the issue of recapture with respect to the present reissue application was discussed. Also discussed was prior art cited by the Examiner against the claims of the present application.

While no definitive agreement was reached with respect to the claims of the present application, the Examiner did agree to consider the positions raised by Applicant at the interview in view of the present amendment and the position submitted herewith.

Independent claim 13 has been amended to now recite that the implantable prosthesis of the present invention includes a biocompatible composition of natural origin within the pores. The biodegradable composition forms a precipitate that substantially fills the pores at selected conditions of temperature and pH to form an insoluble substrate site for cellular attachment. It is respectfully submitted that claim 13 does not violate the recapture doctrine with respect to the

present reissue application, in that claim 13 is narrower in at least one significant aspect as compared with claim 1 as originally filed in the parent application.

In comparing present claim 13 with original claim 1, it is noted that original claim 1 included no limitation with respect to either pH or temperature. Furthermore, original claim 1 included no recitation that the biodegradable composition substantially fills the pores of the implantable prosthesis. Still further, original claim 1 failed to include any limitation with respect to forming a site for cellular attachment.

During prosecution of the parent application which matured into U.S. Patent No. 5,665,114, claim 1 was amended to recite a specific pH limitation of about 7.4. However, issued patent claim 1 fails to include any recitation with respect to the temperature, filling the pores or cellular attachment.

The recapture doctrine seeks to prevent an applicant from recapturing subject matter via reissue which was intentionally abandoned during the original prosecution. This prevents a reissue applicant from using reissue as a means by which to bypass the patent appeals process. However, a reissue claim does not fall within the scope of the doctrine if the reissue claim is materially different from the abandoned claim. The courts have established a test to determine if a proposed reissue claim is materially different from the surrendered original claim. In general, a

reissue claim will not be subject to the doctrine if it is "more restrictive in at least one significant aspect than the canceled claim". In re Richman, 161 USPQ 359, Ball Corp v. United States, 221 USPQ 289.

Furthermore, where a reissue claim is narrower as to one element, but broader as to another element as compared with the abandoned claim, the recapture doctrine does not apply. In re Willingham, 127 USPQ 211. It is thus well established that by restricting a reissue claim in at least one significant aspect with respect to the abandoned claim, the recapture doctrine can be avoided.

As noted above, in the present application, reissue claim 13 differs from original claim 1 in several significant aspects including, *inter alia*, limitations relating to pH and temperature as well as a recitation that the pores of the prosthesis are filled to establish a substrate site for cellular attachment. Accordingly, it is respectfully submitted that under applicable case law the recapture doctrine is not appropriate in rejecting claim 1 under 35 U.S.C. §251. Reconsideration is respectfully requested.

The Examiner has rejected claim 13 under 35 U.S.C. §102(e) as being anticipated by or alternatively under 35 U.S.C. §103 as being unpatentable over U.S. Patent No. 5,290,271 to Jernberg. This determination is respectfully traversed.

As discussed with the Examiner, Jernberg discloses an implantable tubular structure. As known, ePTFE includes a microfiber structure have nodes and fibrils including pores therebetween. Jernberg coats the tubular structure with time-released microparticles containing a chemotherapeutic agent. The microcparticles are designed to release the chemotherapeutic agent into the blood stream over time.

As it relates to claim 13 of the present invention, the chemotherapeutic microparticles of Jernberg do not fill the pores of the ePTFE structure. While there may be some inherent entry of the microparticles into the interstitial spaces between the nodes and fibrils, Jernberg is not designed to fill the pores so as to establish a site for cellular attachment. The microparticles of Jernberg are specifically designed for degradation shortly after implantation within the body. Such degradation would effectively prevent use of the coating material as a site for cellular attachment. In fact, cellular attachment in Jernberg cannot be achieved until the microparticles have actually dissolved. This in direct counterdistinction to claim 13 of the present invention where a biodegradable composition of natural origin is specifically provided to fill the pores and provide an insoluble substrate site for cellular attachment.

As discussed with the Examiner at the interview, Jernberg fails to disclose a biodegradable composition which fills the pores of the prosthesis and which forms an insoluble

substrate site to promote cellular attachment. As such, Jernberg cannot be anticipatory of claim 13 of the present invention.

Furthermore, as the microparticles of Jernberg are designed to degrade so as to release a chemotherapeutic agent to the body, the Jernberg references fails to teach or suggest the use of the microparticles as a insoluble substrate site for cellular attachment. Accordingly, it is respectfully submitted that claim 13 and the claims which depend therefrom are patentably distinct over Jernberg.

Independent claims 1 and 13 are rejected under 35 U.S.C. §102(b) as being anticipated by an article entitled "Plasma Modification and Collagen Binding to PTFE Grafts" by Tran et al. (hereinafter "Tran") or in the alternative under 35 U.S.C. §103(a) as being obvious over Tran in view of U.S. Patent No. 4,193,138 to Okita. This determination is respectfully traversed.

Tran shows a PTFE graft where collagen is applied to the external surface of the graft as a coating. Tran applies the coating by soaking the substrate with collagen material. Tran only discloses the PTFE and does not disclose the use of ePTFE. As such, Tran does not disclose or discuss employing a graft including a porous structure. Since Tran fails to disclose a porous structure, there is no need to discuss the ability to force the collagen material into the pores.

Accordingly, Tran alone fails to anticipate either claims 1 or 13 of the present application which requires a biodegradable composition within the pores of the structure.

Okita is cited for its disclosure of an ePTFE substrate. The structure of Okita is known to include nodes and fibrils defining pores therebetween. Okita includes no disclosure of a biodegradable composition which, at selected conditions of temperature and pH, forms an insoluble substrate site for cellular attachment. Okita specifically discloses adapting the surface of the ePTFE structure in a manner which renders the surface hydrophobic and also provides a polymer in the pores which forms a firmly bonded film of water molecules to prevent absorption of plasma protein which will cause fibrin deposition. (Col. 3, lines 18-27.)

In the present application, the structure recited in claims 1 and 13 is specifically designed to provide a site for cellular attachment by providing a biodegradable composition which fills the pores of the prosthesis. This is in direct opposition to the Okita disclosure of preventing cellular attachment to the PTFE, in that the Okita graft is specifically designed to prevent absorption of plasma protein so as to prevent fibrin deposition. As such, even if Okita was combined with Tran it would still fail to disclose, teach or suggest an implantable prosthesis having a biodegradable composition within the pores which forms a precipitate at selected conditions of temperature and pH to form an insoluble substrate site for cellular attachment. It is therefore

respectfully submitted that claims 1 and 13 are patentably distinct over Tran alone or Tran taken in combination with Okita.

The Examiner has also rejected claims 1 and 13 under under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,197,977 to Hoffman, Jr., et al. (hereinafter "Hoffman") or U.S. Patent No. 5,037,377 to Alonso, both in view of Okita. This determination is respectfully traversed.

Both Hoffman and Alonso show textile grafts. These grafts are formed of fabric having large interstitial spaces into which material may flow. In both Hoffman and Alonso, collagen is shown as being deposited on the graft. Neither Hoffman nor Alonso show expanded PTFE structures including nodes and fibrils defining pores therebetween. Therefore, Hoffman and Alonso each fails to disclose filling ePTFE pores to establish a substrate site for cellular attachment.

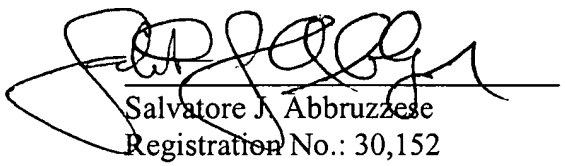
The Examiner has combined the Okita reference with each of Hoffman and Alonso. As noted above, Okita is completely silent on the use of a composition within its pores to promote cellular attachment. In fact, Okita teaches just the opposite. Okita is directed to providing a coating on an ePTFE graft which reduces thrombus formation by preventing absorption of plasma protein which has the tendency to cause fibrin deposition. Accordingly, the combination

of either Hoffman or Alonso taken with Okita fails to disclose, teach or suggest the use of a biodegradable composition substantially filling the pores at selected conditions of temperature and pH to form an insoluble substrate site for cellular attachment. As such, it is respectfully submitted that claims 1 and 13 as well as the claims which depend therefrom are patentably distinct over the cited combination.

Having responded in full to the present Office Action, it is respectfully submitted that the application, including claims 1-18, is in condition for allowance. Favorable action thereon is respectfully solicited.

Should the Examiner have any questions or comments regarding this submission, the Examiner is invited to contact the undersigned attorney at the telephone number given below.

Respectfully submitted,



Salvatore J. Abbruzzese
Registration No.: 30,152
Attorney for Applicant(s)

HOFFMANN & BARON, LLP
6900 Jericho Turnpike
Syosset, New York 11791
(973) 331-1700

VERSION OF AMENDMENT WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

13 (Amended) 13. An implantable prosthesis comprising a body of expanded polytetrafluoroethylene having a structure of spaced apart nodes interconnected by fibrils with pores present between said nodes and said fibrils; and a biodegradable composition of natural origin contained within said pores, said biodegradable composition forming a precipitate that substantially fills said pores at selected conditions of temperature and pH to form an insoluble substrate site for cellular attachment.

17. (Amended) An implantable prosthesis of claim 14 wherein said [chemical solution] composition includes a buffered phosphate.